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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/017,135

12/07/2001

Neil Russell Foster

HILLS1100

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11/01/2006

DLA PIPER US LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,135

Applicant(s)

FOSTER ET AL.

Examiner

Simon J. Oh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and request for continued examination, all received on 08 August 2006.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 August 2006 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejected claim is unclear as to what precisely are the active method steps, in terms of what is actually done that forms the recited particles. Furthermore, although the examiner understands what the applicant means when the applicant states in the response that the particles

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are formed at the point of contact where the solvent stream meets the anti-solvent stream, the claim language itself has become confusing. The examiner suggests that the applicant bring back the deleted phrase of “the method including”, and making clear what the specific methods steps of the instantly claimed process are. The examiner also suggests adding a phrase at the end of the claim that recites the phrase, “whereupon the fine particles of the substance are formed at the point of contact between the non-gaseous fluid and the dense gas”, or something similar.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Debendetti *et al.* (U.S. Patent No. 6,063,910)

The Debendetti *et al.* patent teaches processes for producing microparticles from a solution by anti-solvent re-crystallization using a supercritical fluid (See Column 2, Lines 22-30). Preferred anti-solvent fluids include ethane and ethylene (See Column 2, Lines 39-43). The microparticles can be produced with particle sizes of less than 10 microns (See Column 2, Lines 61-66). In one embodiment, a solution of a soluble material in a solvent is passed through a continuum of supercritical fluid, whereby the soluble material precipitates. The solution may be passed through in the form of droplets, a thin film, or a plurality of fine streams (See Column 2, Lines 44-55). The anti-solvent is introduced at temperatures ranging from 25° to 45°C and 60 to

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200 atm (See Column 5, Lines 33-41). The resulting precipitated particles may then be collected on a suitable collection means (See Column 5, Lines 19-22). The disclosed processes may be used to make particles of proteins, such as insulin (See Example 2; and Claim 8). The particles that are produced appear to be substantially uniform in terms of size and shape (See Figure 6).

The examiner interprets the rejected claims as being product-by-process claims. As such, the product made by the methods disclosed in the prior art read on the limitations of the instant claims, as the resulting product from the disclosure of the prior art is also in the form of fine particles of insulin (a pH-sensitive and biologically active substance) having a particle size of less than 10,000 nm with uniformity of size and shape. The claims are thus rejected for being anticipated by the prior art.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-24 and 27-29 under 35 U.S.C. 103(a) over Merrified *et al.* in view of Manning *et al.* is hereby withdrawn.

Claims 1-24 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debendetti *et al.* (U.S. Patent No. 6,063,910) in view of Merrified *et al.* (PCT Publication No. WO 00/37169)

The Debendetti *et al.* patent teaches processes for producing microparticles from a solution by anti-solvent re-crystallization using a supercritical fluid (See Column 2, Lines 22-

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30). Preferred anti-solvent fluids include ethane and ethylene (See Column 2, Lines 39-43). The microparticles can be produced with particle sizes of less than 10 microns (See Column 2, Lines 61-66). In one embodiment, a solution of a soluble material in a solvent is passed through a continuum of supercritical fluid, whereby the soluble material precipitates. The solution may be passed through in the form of droplets, a thin film, or a plurality of fine streams (See Column 2, Lines 44-55). The anti-solvent is introduced at temperatures ranging from 25° to 45°C and 60 to 200 atm (See Column 5, Lines 33-41). The resulting precipitated particles may then be collected on a suitable collection means (See Column 5, Lines 19-22). The disclosed processes may be used to make particles of proteins, such as insulin (See Example 2; and Claim 8).

The Debendetti *et al.* patent does not disclose the use of a modifying agent in the anti-solvent.

The Merrified *et al.* publication discloses a process and apparatus for the production of particles using a solvent/anti-solvent process in which the anti-solvent is preferably a supercritical fluid (See Abstract). Suitable anti-solvents include ethane and ethylene. The anti-solvent stream may further comprise a modifier, such as methanol and ethanol. Such modifiers alter the intrinsic properties of the supercritical anti-solvent at or around the critical point (See Page 5, Line 19 to Page 6, Line 4). The compressible anti-solvent may be introduced at pressures of 50 to 100 bar at a suitable temperature, which is likely to be in the range of 1.01 T_C to 4.0 T_C (See Page 6, Lines 5-12; and Page 12, Lines 19-25). The apparatus may include a means for collection of the particles, such as a collection chamber (See Page 16, Line 21-29). The particles may be a pharmaceutical material, with a small particle size, such as around 1 to 20 microns (See Page 18, Lines 7-9).

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It would be obvious for one of ordinary skill in the art to combine the disclosures of the prior art in order to obtain the instantly claimed invention. One of ordinary skill in the art would seek to exert a greater degree of control over the processes disclosed by Debendetti *et al.* by the use of modifying agents in the supercritical anti-solvent, as taught by Merrified *et al.* As both prior art references deal with solvent/anti-solvent precipitation processes using a supercritical fluid, they are considered to be analogous art. Therefore, one of ordinary skill in the art would be able to combine the disclosures of the prior art with a reasonable expectation of success. The Debendetti *et al.* discloses that particles are formed when a solution of the material is passed through a continuum of an anti-solvent stream, which is seen by the examiner as reading on the claim limitation that particles are formed upon the contact of a solvent stream with an anti-solvent stream. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 08 August 2006 have been fully considered but they are moot in view of the new grounds of rejection, set forth above.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

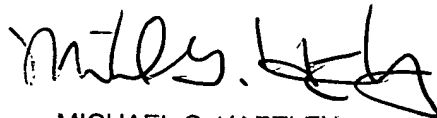
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sj0

A handwritten signature in black ink, appearing to read "m. g. hartley", with a stylized flourish at the end.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER